

Notice of Allowability

Application No.

08/822,033

Examiner

Joseph T. Woitach

Applicant(s)

MARASCO ET AL.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/6/2006.
2. ☒ The allowed claim(s) is/are 1,3-5 and 7-20.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

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DETAILED ACTION

This application is a file wrapper continuation of 08/199, 070, filed February 22, 1994.

Applicants' after final amendment filed September 6, 2006 has been received and entered. Claims 8, 9 13, 14, 15 and 17 have been amended. Claims 2 and 6 have been cancelled. Claims 18-20 have been added. Claims 1, 3-5, 7-20 are pending and currently under examination.

Claim Rejections - 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-5, 7-17 rejected under 35 U.S.C. 103(a) as being unpatentable over Beug *et al.*, Chaudhary *et al.* and Wu *et al.* for the reasons below and as set forth in the previous office action is withdrawn.

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Upon further consideration of Applicants arguments and the declarations made of record in total the rejection is withdrawn. More specifically, Examiner would note that the use of antibodies to bind DNA, and target their delivery were known at the time of filing, however the protein complex to accomplish this was made by chemical means. Upon review of the art of record it is clear that the art would support that the skilled artisan focused on providing better means and methods of chemical linkage. There is no specific teaching in the art to remedy the problems associated with linkage by using a peptide bond and/or addressing these problems by using recombinant means to produce a fusion protein comprising an antibody and a protein that binds a nucleic acid. While recombinant means to produce fusion proteins were known at the time of filing, the present specification is the first to suggest this as a means to address problems of chemical linkage.

Claim 6 rejected under 35 U.S.C. 103(a) as being unpatentable over Beug *et al.*, Chaudhary *et al.* and Wu *et al.* as applied to claims 1, 3-5, 7-16 above, and in further view of Ryder *et al.* is withdrawn.

Claim 6 has been cancelled.

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EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ronald I. Eisenstein on September 13, 2006.

The application has been amended as follows:

In claims 1, 3 and 4 delete -- (2) the nucleic acid segment containing -- and insert “(2) a nucleic acid sequence comprising the nucleic acid segment and” therein.

In claims 13, 15 and 16, in the final line, after ‘transfected with the nucleic acid’ insert “sequence”.

In claims 17, 18 and 19, after ‘wherein the nucleic acid’ insert “sequence”.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

As noted above, while recombinant means to produce fusion proteins were known at the time of filing, the present specification is the first to suggest this as a means to address problems the chemical linkage of an antibody and a nucleic acid binding protein. Upon review of the art of record it is clear that the art would support that the skilled artisan focused on providing better means and methods of chemical linkage. There is no specific teaching in the art to remedy the problems associated with linkage by using a peptide bond and/or addressing these problems by using recombinant means to produce a fusion protein comprising an antibody and a protein that binds a nucleic acid. The motivation to combine the teachings of the cited references comes relied upon by the office has been Beug *et al.* who teach fusion proteins and methods that could be used to generate the fusion protein for the delivery of polynucleotides, however there is no specific motivation to making the invention as claimed.

The present specification provides a disclosure that the claimed fusion protein provides high binding activity and a superior delivery method as compared to the prior art. Further, Applicants have noted that the present disclosure provides support that presently claimed composition versus a chemically linked composition provides for "potentially better binding activity" (page 39 of the specification). Differentiating the claimed invention from the prior art or record, it has also been established that using antibodies instead of receptors as a targeting moiety provides for a more selective and wider range of targeting.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach



JOSEPH WOITACH, PH.D.
PRIMARY EXAMINER